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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/067,870	02/08/2002	Alison Joy Hodgkinson	P64057US2	8119

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EXAMINER	
SZPERKA, MICHAEL EDWARD	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 10/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/067,870	HODGKINSON ET AL.	
	Examiner	Art Unit	
	Michael Szperka	1644	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *47-80* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *47-80* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/424,246.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/8/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election without traverse of the species *Candida albicans* in the reply filed on September 1, 2004 is acknowledged.

Claims 47-80 are pending and under consideration in the instant application.

Priority

2. If applicant desires priority under 35 U.S.C. 120 based upon a previously filed application, specific reference to the earlier filed application must be made in the instant application. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent applications (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

Applicant should amend the first line of the specification to indicate that the instant application is a divisional of U.S.S.N. 09/424,246, filed 2/29/2000, now U.S. Patent No. 6,616,927, which is the national stage entry of PCT/NZ98/00070, filed

5/29/1998, which claims priority under 119(b) to New Zealand application number 314959, filed 05/29/1997.

It is also noted that the foreign priority document, New Zealand application number 314959, filed 05/29/1997 does not disclose the specific antigen *Candida albicans* as capable of being used in the instant invention. Therefore, the priority date for claim 67 is 5/29/1998, the date of filing of PCT/NZ98/00070.

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Applicant's IDS, filed February 8, 2002 is acknowledged. References AP1 and AQ1 have been lined through as information concerning these abstracts, such as the date and author's name are missing.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 47-65 and 69-80 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilson et al. (Immunology, 1972, 23:313-320, see entire document).

Wilson et al. teach that intramammary vaccination of pregnant cows with the bacteria *E. coli* leads to a significant increase in the concentration of IgA in the milk of vaccinated animals that is maintained for at least 28 days (see entire document, particularly Table 2 on page 317). Also taught is that the milk from vaccinated cows can then be ingested by newborn animals to prevent enteric infections (see particularly the second paragraph of page 319). This passive immunization of newborns is consistent with Applicant's description of a pharmaceutical composition as found on page 13, lines 5-19, and as such milk from vaccinated cows *per se* constitutes a pharmaceutical.

Applicant is reminded that the patentability of a product does not depend on its method of production. See MPEP 2113. As such, it is not known how Applicant's process produces a product that is materially different from the one produced by Wilson et al. Therefore, limitations based upon the timing and routes of antigen administration, as well as the addition of adjuvants and antibiotics, have not been considered to lend patentable weight to Applicant's claimed invention.

In view of this, the prior art anticipates the claimed invention.

5. Claims 47-65 and 68-80 are rejected under 35 U.S.C. 102(b) as being anticipated by Sheldrake et al. (Immunology, 1985 56:605-614, see entire document).

Sheldrake et al. teach the production of IgA in the milk of sheep following immunization with a composition comprising the bacteria *Brucella abortus* and the protein antigen ovalbumin (see entire document, particularly page 606, section titled *Immunizations*, first paragraph, and Figure 1). These antigens were prepared in phosphate buffered saline (PBS) and emulsified in Freund's complete adjuvant prior to intraperitoneal injection (page 606, *Immunizations*, second paragraph). Intraduodenal and intramammary antigen administrations were prepared in PBS (page 606, *Immunizations*, second and third paragraphs). Antigen administration via different routes occurred on both the same and different days of the immunization protocol (see page 606, Table 1). Two populations of ewes were used in the study, one being pregnant ewes that had not yet lambed, and the other being ewes eight weeks post partum (page 606, Immunizations, fourth paragraph). As indicated above, milk is considered by Applicant to be a pharmaceutical, and the process by which the immunizations are performed is not seen to alter the structure of the resulting IgA containing milk. Therefore, Sheldrake et al. teach the claimed product, IgA containing ruminant milk produced by immunizing pregnant ruminants, and the prior art anticipates the claimed invention.

6. Claims 47-65 and 69-80 are rejected under 35 U.S.C. 102(b) as being anticipated by Takahashi et al. (J. Dent. Res. 1992, 71:1509-1515, see entire document).

Takahashi et al. teach that immunization of pregnant cows with bacteria leads to the presence of antigen specific IgA in the colostrum and milk of such animals (see

entire document, particularly the *Materials and Methods* section on pages 1509-1510, Tables 1 and 2 on page 1512, the second full paragraph of the right column of page 1511, and the abstract). This milk can be used in human oral passive immunization studies (see particularly page 1509, right column, the first full paragraph). The bacteria used as antigens by Takahashi et al. were prepared in Freund's incomplete adjuvant and were administered to cows as a pool of different bacteria and as individual strains (see particularly page 1510, left column, first full paragraph).

As was stated above, Applicant has claimed a product produced by a defined method, but no evidence has been put forth that the structure of the product, the ruminant IgA contained in the milk, is different from the structure of ruminant IgA in milk produced by another process. Additionally, milk is sufficient to meet Applicant's definition of a pharmaceutical. Therefore, the prior art anticipates the claimed invention.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 47 and 65-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al. (Immunology, 1972, 23:313-320, see entire document) in view of Baley et al. (Pediatrics, 1986, 78:225-232, see entire document).

Wilson et al. teach that immunization of pregnant cows with *E. coli* leads to an increase of IgA in the colostrum and milk up to 28 days after calving (see particularly Tables 1 and 2, page 318, the second full paragraph, and the abstract). Wilson et al. also teach that the enhanced immunoglobulin production of immunized mammary glands could be of practical significance in prophylaxis against enteric infections in newborn animals that ingest milk from immunized mammary glands (see particularly page 319, the second full paragraph). Wilson et al. differ from the claimed invention in that *Candida albicans* is not used as an antigen for vaccination, nor is *Candida albicans* disclosed as an enteric pathogen in newborns.

Baley et al. teach that fungal infections affect 3 to 4% of very low birth weight infants (see entire document, particularly page 225, the introductory paragraph). High incidences of mortality are seen in infants that develop a systemic infection subsequent to initial fungal colonization (see particularly page 229, the section titled Fungal Sepsis). *Candida albicans* is the major infectious species, with colonization within the first week

of life predominantly occurring in the gastrointestinal and respiratory tract (see particularly page 232, the paragraph in the right column). Baley et al. also teach that prevention of early colonization may be a means to reduce the incidence of fungal disease in low birth weight infants (see particularly the last sentence of page 323).

Therefore, one of ordinary skill in the art would be motivated to make IgA containing milk in cows, using the method taught by Wilson et al, substituting *Candida albicans* as the immunizing antigen because *Candida albicans* colonization can occur through the gastrointestinal tract and lead to the development of sepsis in low birth weight infants as taught by Baley et al., and administering milk from immunized cows is a useful treatment for enteric infections in newborns as taught by Wilson et al.

9. Claims 47 and 65-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al. (Immunology, 1972, 23:313-320, see entire document) in view of Cross et al. (J. Am. Vet. Med. Assoc. 1970, 157:1325-1330, see entire document).

Wilson et al. teach a method of immunizing cows to obtain milk that contains an increased concentration of IgA, and that milk from such cows is useful in treating enteric infections in newborn animals (see entire document, particularly Table 2 on page 317 and the second paragraph of page 319). Wilson et al. do not teach immunization with *Candida albicans* and do not indicate that *Candida albicans* can cause enteric infection.

Cross et al. teach that yeasts of the genus *Candida* are known to cause inflammation of the esophagus in mammals, and in cattle they have been associated with mastitis, chronic pneumonia, pathologic vaginal discharges, and aborted fetuses (see particularly page 1325, left column, first paragraph). Cross et al. also specifically

teach the death of a calf diagnosed with candidial rumenitis caused by an infection with *Candida albicans* following antibiotic therapy (see particularly page 1325, left column, second and third paragraphs).

It would have been obvious to a person of skill in the art at the time the invention was made to substitute the antigen *C. albicans* for the antigen used by Wilson et al. Motivation to do so comes from the disclosure that milk from immunized mammary glands can be prophylactic for enteric infections as taught by Wilson et al., and that *C. albicans* is an enteric pathogen for young calves treated with antibiotics as taught by Cross et al. A person of ordinary skill in the art would have a reasonable expectation of success in making this substitution because of the successful use of different antigens to produce antibodies in milk as disclosed by Wilson et al. (see entire document, particularly the section titled Introduction on pages 313-314).

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 47-80 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 47-80 of copending Application No. 10/067,792. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of a pharmaceutical, cosmetic or veterinary composition comprising milk from a ruminant containing IgA as claimed in the instant application is broad and encompasses milk in the form in which it is produced by mammal, as defined on page 6 of the instant specification. A cow makes milk and colostrum as food for a calf. As such, a food or dietary supplement comprising milk from an immunized ruminant containing IgA as is claimed in Application No. 10/067,792 anticipates the claimed invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. No claims are allowable.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is 571-272-2934. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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